REMARKS

I. Introduction

Applicants respectfully request reconsideration of the present application in view of the foregoing amendments and in view of the reasons that follow.

Claim 11 is amended to define Applicants' invention with greater particularity.

Claims 1-2 and 12-21 are canceled without prejudice or disclaimer thereof, having been withdrawn from consideration by the Examiner as being drawn to unelected subject matter. Applicants reserve the right to prosecute the subject matter of these claims in this or another application.

A detailed listing of all claims that are, or were, in the application, irrespective of whether the claim remain under examination in the application, is presented beginning on page 2 with an appropriate defined status identifier.

Upon entry of this Amendment, claims 3-11 will remain pending in the application.

The amendments contained herein do not contain any new matter as they are fully supported by the specification and the claims as originally filed. Because the foregoing amendments do not introduce new matter, entry thereof by the Examiner is respectfully requested.

II. Response to Issues Raised by Examiner in Outstanding Office Action

a. Claim Rejections – 35 U.S.C. § 101

Claim 11 is rejected by the Examiner under 35 U.S.C. § 101 for allegedly being directed to non-statutory subject matter (Office Action, page 4). This claim has been amended pursuant to the Examiner's suggested language. Accordingly, Applicants respectfully request reconsideration and withdrawal of this rejection.

Claims 3-11 are rejected by the Examiner under 35 U.S.C. § 101 for allegedly not being supported by either a specific, substantial and credible asserted utility, or a well established utility. Applicants respectfully traverse this ground for rejection for at least the reasons that follow.

The Examiner asserts that the specification "fails to indicate what disorders are associated with MACP-2" (Office Action, page 4) and that "one would not know what to do with a MACP-2 polynucleotide and a cell proliferative associated disease" (Office Action, page 5).

1. As the Application Teaches that Expression of MACP-2 is Correlated with Proliferative Diseases, and in Particular Prostate Cancer, the Requirement for Utility is Met

Applicants respectfully disagree with the Examiner's assertions. The disclosure indicates cell proliferative diseases in which MACP-2 is expressed. Further, one of skill in the art would know, based on the disclosure in the specification and that which is known in the art, what to do with a MACP-2 polynucleotide and a cell proliferative disorder.

There is support in the specification showing that MACP-2 is expressed in cell proliferative disorders in general, and prostate cancer in particular. For example, a clone of MACP-2 was isolated from a cDNA library (PROSNOT15) derived from a prostate cancer tumor sample (see Table 1 and Table 4 for a description of the library). Furthermore, the nucleotide sequence encoding MACP-2 (SEQ ID NO:7) was found in 71.4% of cDNA libraries that were proliferative in nature (see Table 3). These data suggest a link between MACP-2 and cell proliferative disease, and in particular prostate cancer.

One of skill in the art would recognize from these data that MACP-2 may be useful as a marker in cell proliferative disorders, particularly prostate cancer. Furthermore, the specification suggests that MACP protein levels may be assayed by methods known in the art to determine gene expression. For example, "a variety of protocols for measuring MACP, including ELISAs, RIAs and FACS, are known in the art and provide a basis for diagnosing altered or abnormal

levels of MACP expression" (specification at page 34, lines 11-13). The specification states further that "the polynucleotides encoding MACP may be used for diagnostic purposes" and that "the polynucleotides may be used to detect and quantitate gene expression in biopsied tissues in which expression of MACP may be correlated with disease" (specification at page 34, lines 20-24).

Based on the above, the specification provides a credible utility for the claimed polynucleotides. Accordingly, Applicants respectfully request reconsideration and withdrawal of these rejections.

b. Claim Rejections - 35 U.S.C. § 112, 1st Paragraph (Enablement)

Claims 3-11 are rejected under 35 U.S.C. § 101 allegedly because the claimed invention is not supported by either a well-established or a disclosed specific and substantial credible utility, as set forth in the Office Action at pages 4-6. In rejecting the claims as lacking utility, the Examiner also rejected the claims under 35 U.S.C. § 112, first paragraph alleging the skilled artisan would not know how to use the claimed invention (Office Action, page 7).

Based on the arguments in the preceding section, the application supports a credible utility for the claimed polynucleotides and therefore, the rejection under 35 U.S.C. § 112, first paragraph, for alleged lack of enablement has been rendered moot. Accordingly, Applicants respectfully request reconsideration and withdrawal of the rejection.

c. Claim Rejections - 35 U.S.C. § 112, 1st Paragraph (Written Description)

Claims 4 and 8 are rejected by the Examiner under 35 U.S.C. § 112, first paragraph, for alleged lack of written description. Applicants respectfully request reconsideration and withdrawal of the rejection.

More specifically, the Examiner states that "the specification does not identify any particular portion of the structure that must be conserved" and "the distinguishing characteristics of the claimed genus are not described" (Office Action at the paragraph bridging pages 7 and 8).

Applicants respectfully disagree with this assessment of the specification and point the Examiner to Table 2 at page 51 of the application. There, Applicants disclosed the following residues and domains:

Signature sequences, motifs, and domains:

Signature sequences: G285-S292, C198-C209, C230-C241, C262-C273, C294-C305, C326-C337

Potential glycosylation sites: N88, N245

Potential phosphorylation sites: T319, S105, T215, S362, Y377

This information informs the skilled person of the pertinent portions and characteristics of the polypeptide sequence depicted in SEQ ID NO:2. Furthermore, a polypeptide that shares "90% sequence identity" with SEQ ID NO:2 is one that can accommodate no more than 38 different amino acids (SEQ ID NO:2 contains 379 residues). Armed with this information, therefore, the skilled person would know which residues of SEQ ID NO:2 could be amenable to modification.

In *In re Wallach*, 2002 Pat. App. LEXIS 327 (BPAI, 2002), the Board held that a polypeptide sequence alone puts one in possession of all of the entire genus of polynucleotide variants that could possibly encode that polypeptide, and that it is unnecessary to provide written description support for each and every one of those polynucleotide species.

Just as there exists degeneracy of the DNA code, there similarly exists amino acid substitutions that can be made to a polypeptide, which are conservative in nature and which do not alter the basic properties of the residue that is replaced. For instance, a glycine or a serine residue can replace an alanine residue. Applicants disclose at page 13, lines 26-28, what "conservative changes" are and that computer programs well known in the art (e.g., Lasergene)

can assist the skilled artisan in determining which residues may be substituted within a polypeptide sequence without disrupting function.

Analogous arguments can be made for claim 8 which is directed to polynucleotide variants having at least 90% sequence identity to SEQ ID NO:7 (the polynucleotide encoding SEQ ID NO:2). Using routine methods of sequence comparison, one of skill would readily recognize a sequence having a minimum of 90% identity to SEQ ID NO:7. Further, the structural attributes described above would also apply to the polynucleotide regions encoding those attributes.

Based on the above, the written description requirement is fully satisfied for the scope of claims 4 and 8. Accordingly, Applicants respectfully request reconsideration and withdrawal of these rejections.

d. Claim Rejections - 35 U.S.C. § 112, 2nd Paragraph

Claim 5 is rejected by the Examiner under 35 U.S.C. § 112, second paragraph, as being allegedly indefinite. The Examiner asserts "the term 'stringent conditions' is unclear because it is a relative term, subject to individual interpretation" (Office Action, page 10).

Claim 5 is clear as written because this term is well described in the specification and is known to those of skill in the art. See for example,

> "stringent salt concentration will ordinarily be less than about 750 mM NaCl and 75 mM trisodium citrate, preferably less than about 500 mM NaCl and 50 mM trisodium citrate, and most preferably less than about 250 mM NaCl and 25 mM trisodium citrate." (page 16, lines 6-9); and
>
> "stringent temperature conditions will ordinarily include temperatures of at least about 30°C, more preferably of at least about 37°C, and most preferably of at least about 42°C" (page 16, lines 11-13).

Furthermore, the specification cites references in which hybridization stringency conditions are discussed (e.g., Wahl et al., (1987) *Methods Enzymol.*, 152:399-407; Kimmel, A.R. (1987) *Methods Enzymol.*, 152:507-511, at page 16, lines 4-6, of the specification). One of skill in the art would use the descriptions in the specification and the teachings of the art and readily understand the meaning of "stringent conditions."

Accordingly, Applicants respectfully request reconsideration and withdrawal of this rejection.

CONCLUSION

The present application is now in condition for allowance. Favorable reconsideration of the application as amended is respectfully requested.

The Examiner is invited to contact the undersigned by telephone if it is felt that a telephone interview would advance the prosecution of the present application.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 C.F.R. §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 19-0741. Should no proper payment be enclosed herewith, as by a check being in the wrong amount, unsigned, post-dated, otherwise improper or informal or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 19-0741. If any extensions of time are needed for timely acceptance of papers submitted herewith, Applicants hereby petition(s) for such extension under 37 C.F.R. §1.136 and authorizes payment of any such extensions fees to Deposit Account No. 19-0741.

Respectfully submitted,

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By _____

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